Denial of AWA License Applications

References: AWA Section 3 and 9 CFR, Part 2, Sections 2.1, 2.5, 2.10, 2.11

History: This replaces the September 3, 1992 memo entitled "Denial of AWA License Applications."

Justification: Under the Animal Welfare Act (AWA) regulations and standards, the Animal & Plant Health Inspection Service (APHIS), Animal Care (AC) can deny an AWA license application under certain restricted circumstances. This policy serves to clarify when a license application can be denied, and when and what it means for a license to be invalid.

Policy:

The Investigative & Enforcement Services (IES) staff has met with the Office of General Counsel (OGC) and identified the following situations where the denial of a license is appropriate:

a. Failure of new applicant to pass three compliance inspections within 90 days of first inspection as specified in Section 2.3(b) or to comply with the regulations and standards as specified in Section 2.11(a)(3).

The Animal Care Regional Director (ACRD) will issue a letter (attached) to the applicant informing him/her of APHIS' denial of his/her license application. The denial letter will notify the applicant of his/her right to a formal administrative hearing to show why the application should not be denied as required in Section 2.11(b). The letter will also inform the applicant of the procedures required to request a hearing. The license denial will remain in effect until the final legal decision. Once a hearing is requested, IES will be responsible for compiling a case of existing evidence and submitting it through the ACRD to the IES staff within a short period of time. The IES staff will coordinate with OGC to arrange a hearing date.

b. Applicant has been fined or sentenced to jail under State or local animal cruelty laws as specified in Section 2.11(a)(4).

IES will prepare a case file documenting the evidence from the State or local case including a copy of the court's decision and sentence levied. The ACRD will inform the applicant of APHIS' denial of license application with a letter. The letter will contain information on the applicant's right to a hearing and procedures to initiate the process. Once a hearing is requested, the ACRD will immediately submit the case to IES staff. The IES staff will coordinate with OGC to arrange a hearing date.

c. Applicant is under investigation by State or local authorities for animal cruelty.

IES will conduct an investigation and collect evidence to substantiate or refute the allegations. The evidence should include information collected by State or local investigators in addition to corroborating evidence from interviews and/or AC inspections. The ACRD will submit the case to the IES staff for review and forwarding to OGC. If OGC concurs with the denial, IES staff will notify the ACRD. The ACRD will issue a letter informing the applicant of the denial of license application. The letter will contain information on the applicant's right to a hearing and procedures

to initiate the process. If a hearing is requested, the ACRD will submit the case to IES staff. The IES staff will coordinate with OGC to arrange a hearing date.

What is a "valid" license?

A license shall be considered valid and effective unless:

a. The license has been revoked or suspended. b. The license is voluntarily terminated by the licensee in writing. (This may include notation of the surrendering of the license to the inspector on the APHIS inspection form.) c. The license has expired. d. The applicant has failed to pay the application and appropriate annual licensing fee.

Licenses are issued for specific premises and are not valid at a different location.

Sample License Denial Form Letter:					
Dear:					
This letter is to inform you that your application for a license under the Animal Welfare Act (7 U.S.C. 2131 et seq.) is denied pursuant to Section 2.11 of the regulations (9 C.F.R. 2.1 et seq.) for the following reason(s):					
Failure to comply with the requirements of Section 2.1 of the regulations (9 C.F.R.					
2.11(a)(1)). Failure to comply with the requirements of Section 2.2 of the regulations (9 C.F.R.					
2.11(a)(1)). Failure to comply with the requirements of Section 2.3 of the regulations (9 C.F.R. 2.11(a)(1)).					
Failure to comply with the requirements of Section 2.4 of the regulations (9 C.F. R. 2.11(a)(1)).					
Failure to comply with the requirements of Section 2.6 of the regulations (9 C.F.R. $2.11(a)(1)$).					
License has been revoked or is currently suspended as set forth in Section 2.10 of the regulations (9 C.F.R. 2.11(a)(3)).					
Has been fined, sentenced to jail, or pled nolo contendere (no contest) and paid a penalty under State or local cruelty to animal laws within 1 year of application (9 C.F.R. 2.11(a)(4)). Has made false or fraudulent statements or has provided false or fraudulent records to the Department (9 C.F.R. 2.11(a)(5)).					
You may request a hearing in accordance with the applicable Rules of Practice for the purpose of showing why your application for a license should not be denied. You must notify this office, in writing by certified mail, within 20 days from receipt of this letter if you desire a hearing, and a hearing will be held in due course. Failure to request a hearing within 20 days from receipt of this letter will be deemed a waiver of such hearing.					
If you have any questions with reference to this matter, please do not hesitate to contact this office by mail or by phone at					
Sincerely,					

References: AWA Sections 10, 17 and 9 CFR, Part 2, Sections 2.8, 2.126

History: This is a new policy statement, to remain in effect until enacted into regulatory changes.

Justification: The Animal Plant & Health Inspection Service (APHIS), Animal Care (AC) has been provided the authority to require whatever records or reports are needed to effectively enforce the Animal Welfare Act (AWA). In order for licensed traveling facilities to comply with the requirement of readily available access to the premises by the APHIS inspector, APHIS must be kept apprised of the location of the facility.

Policy:

Exhibitors who are in continuous travel status shall update their itinerary as often as necessary to ensure AC knows their whereabouts at all times.

Circuses, petting zoos, and acts with an established route shall notify AC in advance of departing their home facility and update travel information as needed.

Exhibitors who take animals from their facilities from time to time shall notify AC when any animal is gone more than four (4) consecutive days. Upon request, a licensee shall provide an itinerary of absences of less than four (4) days.

Providing notification ensures the opportunity for access for an unannounced inspection, eliminates unnecessary AC visits when a licensee has been inspected recently, and minimizes resources needed to locate the exhibitor.

The itinerary should provide the following:

- 1. Dates away from home facility
- 2. City and State for all stops
- 3. Site name or location of all stops

Similar information must be provided for all periods of "lay-over" while traveling. The licensee may provide this information to AC by any of the following methods:

- a. Mail information to the Regional office or inspector
- b. Fax information to the Regional office or inspector
- c. Voicemail information to the inspector
- d. E-mail information to the Regional office

Notice must be made in advance of travel and updated as needed.

Expired Medical Materials
Pharmaceutical-Grade Compounds in Research
Surgery
Pre- and Post-Procedural Care
Program of Veterinary Care
Euthanasia

References: AWA Section 13 and 9 CFR, Part 2, Sections 2.31, 2.32, 2.33, 2.40 and 9 CFR, Part 3, Section 3.110

History: Provides requested guidance. Replaces memoranda dated May 31, 1990, November 29, 1991, April 6, 1992, and September 25, 1992.

Justification: The Animal Welfare Act (AWA) requires that all regulated animals be provided adequate veterinary care.

Policy:

Expired Medical Materials

The use of expired medical materials such as drugs, fluids, or sutures on regulated animals is not considered to be acceptable veterinary practice and does not constitute adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act. All expired medical materials found in a licensed or registered facility are to be brought to the attention of the responsible official. The facility must either dispose of all such materials or segregate them in an appropriately labeled, physically separate location from non-expired medical materials. The Animal & Plant Health Inspection Service (APHIS) has no jurisdiction over facilities using expired medical materials for non-regulated animals or non-regulated activities. For acute terminal procedures, APHIS does not oppose the use of expired medical materials if their use does not adversely affect the animal's well-being or compromise the validity of the scientific study. Proper anesthesia, analgesia, and euthanasia are required for all such procedures. Drugs administered to relieve pain or distress and emergency drugs must not be used beyond their expiration date. Facilities allowing the use of expired medical materials in acute terminal procedures should have a policy covering the use of such materials and/or require investigators to describe in their animal activity proposals the intended use of expired materials. The attending veterinarian and the Institutional Animal Care and Use Committee (IACUC) are responsible for ensuring that proposed animal activities avoid or minimize discomfort, distress, and pain to the animal. These responsibilities cannot be met unless the veterinarian and the IACUC maintain control over the use of expired medical materials.

Pharmaceutical-Grade Compounds in Research

Investigators are expected to use pharmaceutical-grade medications whenever they are available, even in acute procedures. Non-pharmaceutical-grade chemical compounds should only be used in regulated animals after specific review and approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product. Cost savings alone are not an adequate justification for using non-pharmaceutical-grade compounds in regulated animals.

Surgery

AWA regulations require that survival surgeries be performed using aseptic techniques and that major operative procedures on nonrodents be performed only in dedicated surgical facilities. Nonsurvival surgeries require neither aseptic techniques nor dedicated facilities if the subjects are not anesthetized long enough to show evidence of infection. Research facilities doing surgical demonstrations while traveling must use aseptic techniques and dedicated surgical facilities. Motel meeting rooms and auditoriums do not qualify as dedicated surgical facilities. Nonsurvival surgeries not performed aseptically or in a dedicated facility must at least be performed in a clean area, free of clutter, and using acceptable veterinary sanitation practices analogous to those used in a standard examination/treatment room. Personnel present in the area must observe reasonable cleanliness practices for both themselves and the animals. Eating, drinking, or smoking are not acceptable in surgery areas, and locations used for food handling purposes do not qualify as acceptable areas for performing surgeries.

Pre- and Post-Procedural Care

All animal activity proposals involving surgery must provide specific details of pre- through post-procedural care and relief of pain and distress. The specific details must be approved by the attending veterinarian or his/her designee. However, the attending veterinarian retains the authority to change post-operative care as necessary to ensure the comfort of the animal. The withholding of pain and/or distress relieving care must be scientifically justified in writing and approved by the IACUC. The appropriate use of drugs to relieve pain and/or distress must be specified in the animal activity proposal to avoid possible delays due to investigator concerns that a treatment regimen may interfere with the study. Furthermore, the specified drugs for relief of pain and/or distress must be readily available for use as described in the proposal. While an animal is under post-surgical care, the ownership of the animal is not to change. If the animal is taken to an off-site location, such as a farm, for post-operative care, that location should be identified as a site of the research facility. An animal is not to be taken to an off-site location before it fully recovers from anesthesia unless justified in the animal activity proposal. Appropriate post-operative records must be maintained in accordance with professionally accepted veterinary procedures regardless of the location of the animal.

Program of Veterinary Care

Facilities which do not have a full-time attending veterinarian must have a written Program of Veterinary Care (PVC). This Program must consist of a properly completed APHIS Form 7002 or an equivalent format providing all of the information required by the APHIS form. The attending veterinarian must visit the facility on a regular basis, i.e., often enough to provide adequate oversight of the facility's care and use of animals but no less than annually. The PVC must be reviewed annually and updated whenever necessary (e.g., as a new species of animal or a new attending veterinarian is obtained, or the preventive medical program changes). It must be initialed and dated by both the attending veterinarian and the facility representative whenever it is changed or reviewed without change. The preventive medical program described in the PVC is expected to be in accordance with common good veterinary practices (e.g., appropriate vaccinations, diagnostic testing). It should include zoonotic disease prevention measures and, if necessary, special dietary prescriptions.

Euthanasia

The method of euthanasia must be consistent with the current Report of the AVMA Panel on Euthanasia. Gunshot is not an acceptable method of routine euthanasia for any animal. Gunshot as a routine method of

euthanasia not only endangers surrounding animals, buildings, and personnel, but it is likely to cause distress to other animals. It should only be used in situations where other forms of acceptable euthanasia cannot be used (such as emergency or field conditions where the animal cannot be appropriately restrained) or in cases where gunshot will reduce danger to other animals or humans. Only personnel skilled in the use of firearms, using appropriate firearms, and familiar with the "kill point" of an animal should perform the euthanasia. If the firearm is not aimed so that the projectile enters the brain and causes rapid unconsciousness and subsequent death without evidence of pain or distress, this method does not meet the definition of euthanasia. (All State and local laws relevant to gunshot must also be met.)

References: AWA Sections 12, 13 and 9 CFR, Part 2, Section 2.6

History: This replaces the March 6, 1992 memo entitled "Use of Leased or Rented Animals by Licensees."

Justification: When leased animals are used by another licensee, the responsible party or parties need(s) to be consistently identified in the event of alleged Animal Welfare Act (AWA) violations involving those animals. This policy serves to clarify this issue.

Policy:

Animals are subject to AWA jurisdiction when they are used in regulated activities. Animals that are leased are still regulated, even if they are not in the custody of their owners.

Both lessee and lessor must be licensed, as indicated in 9 CFR, Section 2.6, which describes that lessee and lessor shall both pay a fee as dealer, or lessee and lessor shall both include the animals held when calculating the required fees as an exhibitor.

Exhibitors and dealers must keep records which identify animals they own, hold for others, or keep in their possession or under their control.

The Regional Director is authorized to grant an exemption from licensing when issuing a license would not effectuate the purposes of the Animal Welfare Act, e.g., one-time use of a non-performing animal for the purpose of making an advertisement.

Policy #5 — Licensing of Exotic Animal Auction Markets — April 14, 1997

References: AWA Section 12 and 9 CFR, Part 2, Section 2.1, 2.6 and 9 CFR, Part 3, Subpart F

History: This replaces the February 1, 1991 memo entitled "Licensing of Exotic Animal Auction Markets."

Justification: Until the proposed exotic animal auction regulations are cleared and published, guidelines are needed to address these growing markets.

Policy:

All auction markets that sell exotic or wild animals are required to be licensed.

The market operator is responsible for compliance with all regulations and standards, including transportation standards, once the animals are accepted by the auction market.

If the consignor is licensed, compliance will be the responsibility of both the licensee and the market.

The standards for record keeping, transportation, cleaning, sanitation, and general animal health and well-being will be monitored and enforced.

Incompatible animals are not to be held in the same enclosure or close to other animals that may cause them stress.

All caged and/or dangerous animals must be held in a manner that ensures the safety of the animals and the public.

A species-appropriate containment area is required around the loading and unloading areas to prevent the escape of animals.

References: AWA Section 13 and 9 CFR Part 3 Sections 3.6, 3.8, 3.28, 3.53, 3.80, 3.104, 3.128

History: This replaces the June 6, 1984 memo entitled "Traveling Animal Acts-Cage Spaces for Dogs, Cats, and Nonhuman Primates." It expands and clarifies enclosure space and exercise requirements for traveling exhibitors.

Justification: Some traveling exhibitors maintain animals long term in transport cages during "travel status." This policy clarifies when the licensee is required to meet full primary enclosure space requirements and/or provide sufficient exercise space and time for animals in traveling exhibits.

Policy:

Animals exhibited in traveling shows may be kept in enclosures that meet the space requirements for transport enclosures as specified in Sections 3.14, 3.36, 3.61, 3.87, 3.113, and 3.137 **ONLY** during actual transport, i.e., movement in a conveyance between temporary locations. At all other times, they must be provided with space as described below.

- Dogs, cats, rabbits, guinea pigs, hamsters, nonhuman primates, and marine mammals must be housed in primary enclosures that meet the space requirements described in Sections 3.6, 3.28, 3.53, 3.80, and 3.104, respectively.
- Primary enclosures for all other animals must, at a minimum, allow space for each animal to express all species-typical postures, social adjustments, behaviors, and movements. For example, animals must be able to lie down with limbs extended in a normal manner without obstruction from enclosure sides or having to extend feet through feeder doors or bars. Animals that normally engage in occasional vertical postures, such as bears and many felines, must have sufficient vertical space available to accommodate these postures.
- When elephants are housed on chains while not in transport, the chains must be of sufficient length and arrangement so as to permit each elephant to comfortably lie down, get up, self-groom, and move about within a reasonable range. If elephants are kept unchained in a truck or railway car, each elephant must have enough space to make these postural adjustments as well. These same requirements apply to tethered hoofstock.
- When more than one animal is kept in an enclosure at one time, all animals must simultaneously have sufficient space to accommodate the postures and movements as described above.
- Subpart F animals including, but not limited to, elephants, hoofstock, and exotic cats, must be released regularly from the primary enclosure or tether into a secure space, such as a ring or corral, that provides the opportunity for species-appropriate exercise. This must occur at least once a day for an appropriate length of time unless otherwise justified. These periods will be in addition to regular performances and practice time. An area enclosed by an electric fence is acceptable for this purpose if monitored at all times. Trained elephants and domestic hoofstock may be walked by a qualified handler for this purpose.

References: AWA Section 13 and 9 CFR, Part 3, Section 3.80.

History: Replaces July 31, 1991 policy entitled "Clarification of Owl Monkey as a Group 2 Species," and June 30, 1992, letter regarding classification of tree shrews.

Justification: Clarification is needed to specify group classifications for various species of nonhuman primates in order to determine proper space requirements.

Policy:

In reference to space requirements under Section 3.80, the following will apply:

- Group 2 will include adult owl monkeys (*Aotus* spp.) and squirrel monkeys (*Saimiri* spp.) regardless of adult weight.
- Group 3 will include adult crab-eating macaques (*Macaca fascicularis*) regardless of adult weight. They are also known as cynomolgus macaques.
- Group 6 will include adult:
 - a. spider monkeys (Ateles spp.)
 - b. woolly spider monkeys (Brachyteles spp.)
 - c. woolly monkeys (*Lagothrix* spp.)
 - d. gibbons and siamangs (Hylobates spp.)

These species have been designated as brachiating since this term applies to any primate whose form of locomotion involves using its arms, legs, and/or tail while its body is suspended. The intent of the space regulations is to provide sufficient space for all species-typical postural and locomotive behaviors. Since each of these species engages in brachiating-type movement, they require the larger space provided for Group 6 primates.

Tree Shrews-The scientific community has removed tree shrews from the Suborder Prosimii. Therefore, they are no longer classified as primates and are not required to meet space or environmental enrichment requirements for primates.

References: AWA Section 16 and 9 CFR, Part 2, Section 2.19

History: This replaces August 17, 1992, REAC Memorandum No. 990, entitled, "Guidelines for Confiscation and Destruction of Animals."

Justification: Under the Animal Welfare Act (AWA), the Animal Plant & Health Inspection Service (APHIS), Animal Care (AC) is authorized to confiscate and destroy regulated animals if they are suffering. This guideline specifies the protocol for such action.

Policy:

If animals are found to be suffering and relief has not been provided by the licensee or registrant, and with all due consideration to the provisions of Section 2.38(e), *Confiscation and Destruction of Animals* at reseach facilities, this policy provides instructions to:

- a. Require the licensee or registrant to provide proper care and relief as soon as possible, but not to exceed 24 hours.
- b. Confiscate the animal and/or make arrangements for relief, relocation or euthanasia.

I. Determination of Suffering

- A. Recognition of suffering Veterinary Medical Officers (VMO) and Animal Care Inspectors (ACI) are qualified to recognize a suffering animal. If the determination is made that the animal is suffering, such determination must be confirmed by an Animal Care (AC) veterinarian. If possible, suffering should be confirmed by two AC veterinarians. The determination must be documented with a complete inspection to include photographs and/or other physical evidence as may be required. A private veterinarian may also be requested to examine the animal. If it is determined that the animal is not suffering, document any noncompliant items and set a deadline for correction. In all cases, the documentation shall included the completion of the appropriate APHIS inspection forms, citing the noncompliance(s) in detail.
- B. <u>Disagreement that an animal is suffering</u>- If the owner/manager/responsible person, hereafter referred to as "responsible person," disagrees with the written notification by the AC representative that the animal is suffering, he/she may call in a qualified veterinarian for a second opinion. This must be done as soon as possible within the maximum time frame of 24 hours, so as not to jeopardize the health and well-being of the animal. This is subject to approval by the AC representative. The second opinion will be considered ONLY if the veterinarian provides a signed written statement to the responsible person and to the AC representative indicating the following:
 - 1. Time and place of examination
 - 2. Number and species of animal(s) examined
 - 3. Examination findings and tentative diagnosis
 - 4. Recommended treatment or course of action, including euthanasia
 - 5. Time and method of treatment or euthanasia administered or a statement that the animal(s)
 - is healthy and sound and that veterinary care or euthanasia is not required
 - 6. Any recommended follow-up treatment or action

If AC disagrees with the veterinarian's findings, the Animal Care Regional Director (ACRD) may obtain the assistance of a non-APHIS veterinarian experienced with the species of animal involved. The final decision in determining animal suffering shall be the decision of the ACRD based upon the findings of the AC veterinarian and/or expert involved. The ACRD shall maintain contact with the responsible person until the matter is resolved.

C. Agreementthat an animal is suffering- The responsible person should immediately provide the necessary relief, veterinary care, or euthanasia, within the time frame specified which should not exceed 24 hours. If the animal is an endangered species or a marine mammal, the AC representative should also comply with the requirements of the cooperative agencies (see Section III - "Procedures for Confiscation and Destruction of Suffering Animals" of this policy). The animal may be disposed of on the licensee's premises or the registrant's facility, provided such disposal complies with all local, State and Federal laws. Follow-up is essential to verify this part has been accomplished to AC satisfaction. The ACRD shall maintain contact with the responsible person until the matter is satisfactorily resolved.

II. Notification

A. <u>Notification of Owner</u> - If it is determined that the animal is suffering and in need of veterinary care, the AC representative (with the approval of the ACRD) should immediately notify the responsible person, both verbally and in writing, and request correction of the problem. Copies should be forwarded immediately to the AC Regional office. This notification must include the following:

- 1. Number and species of animal(s) found to be suffering and individual identification number (for dogs or cats) or brief description of each animal.
- 2. Identification of deficiencies or areas of noncompliance causing the suffering.
- 3. Steps that must be taken to correct the problem and alleviate the suffering.
- 4. Current location of the premises or transport conveyance.
- 5. A statement that the animal shall not be removed from the premises or location without APHIS, AC permission.
- 6. The time period in which the animal is to be given relief and adequate care. This time period must be as soon as possible after determining the animal is suffering and in need of veterinary care, but no later than 24 hours.
- 7. The signature of the licensee accepting this notification. (If the responsible person refuses to sign, the AC representative must document the issuance of this notification by a sworn statement.)

Follow-up notification will be accomplished by the ACRD.

- B. Notification of the Deputy Administrator Notification will be forwarded through the Assistant Deputy Administrator for Animal Care (ADAAC) to the Deputy Administrator (DA), AC, as soon as possible. A copy of the notification to the owner should be faxed to AC Headquarters.
- C. Notification of Investigative & Enforcement Services (IES) Contact the IES Regional Director (IESRD) for assistance prior to the official notification of the responsible person, if possible. The IES investigator should assist in documentation of violations and suffering during examination by AC.

III. Procedures for Confiscation and Destruction of Suffering Animals

A. Responsible person

- a) <u>Failure to act by the responsible person</u> The responsible person is required to give relief to the animal or provide euthanasia as soon as possible, but no later than 24 hours after formal notification. If the person fails to do so, APHIS should begin confiscation procedures as specified below.
- b) Responsible person is unavailable When the AC and IES representatives have reason to believe that the animal is suffering and the responsible person for the animal cannot be found after a reasonable time (24 hours), except in extreme cases, the IES investigator shall contact local law enforcement for assistance, and the AC veterinarian shall contact a qualified veterinarian to accompany them to the premises. The veterinarian and the AC representative shall determine whether or not the animal is suffering, diagnose the problem and probable cause, and document the findings and recommendations in writing. The AC representative shall ensure that adequate care is provided to the animal. If the condition of the animal cannot be corrected by this temporary care, the AC representative shall confiscate the animal in accordance with this policy.
- B. <u>Obtain authority to confiscate</u> If any animal (as defined in 9 CFR, Subchapter A, Part 1, Section 1.1) is subject to confiscation or euthanasia due to suffering and lack of care, the AC representative, after informing the responsible person in writing, shall immediately inform the ACRD.

The ACRD shall take the following actions:

- 1. Notify the DA, AC, through the ADAAC, that confiscation may be in order.
- 2. If it is deemed necessary, obtain the opinion of a second AC VMO.
- 3. If necessary, obtain an opinion of a non-APHIS veterinarian experienced with the species of animal involved.
- 4. Coordinate all proposed legal actions (subpoenas, etc.) with the IES staff.
- 5. Request assistance with procedures for confiscation from the IESRD.
- 6. When a decision is made that confiscation is in order, notify the Deputy Administrator, AC, through the ADAAC.

The ADAAC shall, through the DA, AC, seek approval from the APHIS Administrator concerning confiscation of the animal(s) under the authority of Section 16(a) of the Act, and as provided in Sections 2.129 and/or 2.38 of the regulations.

- C. <u>Endangered species or marine mammals</u> If the suffering animal subject to confiscation is an endangered species or a marine mammal, the AC representative will advise the ACRD. The ACRD will notify the ADAAC. The ADAAC shall inform the DA, AC, who will inform the Department of the Interior, the Department of Commerce, and/or other appropriate cooperating services as required in Sections 2.38 and 2.129(c), and by any functioning Interagency Agreement.
- D. <u>Arranging for facility to hold confiscated animal</u> The confiscated animal may be held by AC on the premises, provided that the premises comply with AWA standards and regulations. AC shall maintain constant supervision of the confiscated animal on the premises. If the confiscated animal cannot be held on the premises, the ACRD should arrange for transportation and transfer of the animal to licensees or registrants who are in compliance with the AWA regulations and standards, or humane agencies, animal shelters, or pounds. The ACRD should ensure proper care, holding, treatment or euthanasia of the animal at the facility receiving the confiscated animal.

- a) With approval of responsible person If it is deemed necessary, the IES investigator may request the local police, sheriff, or U.S. Marshal to accompany him/her and the AC representative to the premises (as provided in Sections 2.38 and 2.129) for the purpose of confiscation. The IES representative shall serve oral and written notice to the responsible person for the suffering animal that AC is seizing the animal under the provisions of the AWA, Section 16(a), and the regulations and standards, Sections 2.38 and 2.129. The IES representative shall read these sections and serve a copy to the responsible person. The responsible person (if agreeable) shall sign a statement surrendering the custody and rights of the animal to APHIS for disposition (this is not a requirement.).
- b) Without approval of the responsible person If the responsible person will not sign a statement surrendering the animal, the IES investigator may, if it is deemed necessary, contact local law enforcement officials or the U.S. Marshal to effect the seizure of the animal without the responsible person's signature of approval and arrange for facilities to hold the confiscated animal, as stated previously in this policy.

IV. Disposition of Confiscated Animal

The ACRD shall arrange, at APHIS' expense, subject to recovery from the responsible person, the following provisions:

- 1. Transportation of the confiscated animal, which meets all standards as required for that species of animal, including trained animal handlers and tranquilization or sedation if required
- 2. A premises, kennel, or other facility which meets the standards, and which may house or contain the confiscated animal until it is disposed of or destroyed
- 3. The services of veterinarians knowledgeable in the species involved, caretakers, handlers or truck drivers as required
- 4. Feeding, care, veterinary treatment or euthanasia

The ACRD may seek the cooperation of local humane organizations, zoos, and shelters for the use of their transportation, personnel, and other facilities at no expense to the public or to APHIS when possible. all liabilities. If for any reason, the confiscated animal cannot be moved to other premises, it should be provided the care required to ensure relief and treatment, or euthanized and disposed of, as necessary. All local, State and Federal regulations, including environmental protection regulations, should be followed when disposing of a confiscated animal.

An animal that is not to be returned to the owner, and that does not require euthanasia, will be placed in another facility at no cost to APHIS whenever possible. If it cannot be placed after a reasonable time, it will be euthanized.

V. Guidelines for Billing and Reimbursement for Confiscation of Animal

The following procedure is to be used to collect from the responsible person(s) and make reimbursement for the confiscation of animals (veterinary care, transportation, housing, feeding, handlers and other related expenses). This should not include staff hours, travel, etc., by USDA personnel.

1. Regional offices will prepare a memo to the APHIS Field Service Office (FSO), Accounting Section, requesting that payment be made for expenses incurred for confiscation of animals and also reimbursement of costs from responsible persons. Refer to the attached memo, "Billing and Collection for Confiscated Animals."

2. FSO will have the responsibility of billing and collecting from responsible persons and for making payment to veterinarians, transporters, handlers, etc., for care of the animal.

VI. Documenting an Alleged Violation

After relief to the suffering animal has been provided by the facility or through confiscation, IES will document all apparent violations of the AWA which led to the suffering of the animal. This report shall be submitted by the ACRD as an alleged violation to the IES staff within 15 calendar days after the completion of the confiscation procedures.

VII. Summary suspension of license and injunctive relief

An immediate summary suspension of the license, as provided in the AWA, Section 19, may be recommended by the ACRD at this time.

The request should be made immediately by the ACRD by telephone to the IES Staff Director and supported by a preliminary report prepared by IES, documenting evidence that the Act, regulations, and/or standards have been violated. The evidence shall be submitted by the ACRD as an alleged violation to the IES staff.

Notice of Confiscation of Animals					
TO:					
Notice is hereby given that the following animals (list attached) are hereby confiscated by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, pursuant to the authority of Section 16 of the Animal Welfare Act (7 U.S.C. 2146) and Title 9, Code of Federal Regulations, Section 2.129 (9 C.F.R. 2.129), for failure to provide necessary care for the animals. Animal Care					
Animal and Plant Health Inspection Service U.S. Department of Agriculture By:					

Notice is hereby given that the animals identified on the attached inspection report dated ________, are subject to confiscation by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, and may be confiscated unless the instructions given in the report are followed. Such action is authorized by Section 16 of the Animal Welfare Act (7 U.S.C. 2146) and Title 9, Code of Federal Regulations, Section 2.129 (9 C.F.R. 2.129). Should you need further information, you may contact ______ at _____ (phone number). Animal Care Animal and Plant Health Inspection Service

Notice of Intent to Confiscate Animals

U.S. Department of Agriculture

By:_____

Sample

Date:

Subject: Billing and Collection for Confiscated Animals

To: Accounting Section Field Servicing Office Minneapolis, MN

Please make payment to John Doe, File No. 12345, City, State, in the amount of \$999.99 (bill enclosed), and charge accounting code 12345-67890.

John Doe provided examination, evaluation, euthanasia, and necropsy services on June 1, 2, 3, and 4, 1992, for the animal(s) confiscated from Jack Smith, 1234 Main Street, City, State. Refer to 9 CFR, Animal Welfare, Section 2.129 (a), (b), and (c).

Also, please bill for collection Jack Smith at the above address using the following statement of charges:

All costs for providing care, treatment, euthanasia, or disposition of confiscated animals (as provided in Section 2.129 (a), (b), and (c) of the 9 CFR) shall be reimbursed by the person responsible for the animal(s).

Enclosed is a bill for professional services provided by John Doe on June 1, 2, 3, and 4, 1992, in the amount of \$999.99.

When funds are received, please deposit them back to Accounting Code 12345-67890.

Name Regional Director Regional Office, Animal Care

Enclosure

cc: Resource Management Support, IES, and AC, Riverdale, MD Claims and Payments, FSO, Minneapolis, MN

Policy #9 — Barrier Facility SPF Colony Inspection — April 14, 1997

References: AWA Section 16 (a) and 9 CFR, Part 2, Sections 2.38(b), 2.1

History: Provides requested guidance. Replaces letter dated July 5, 1991.

Justification: The Animal & Plant Health Inspection Service (APHIS) must have access to inspect all covered animals at a regulated facility to ensure compliance with the Animal Welfare Act (AWA).

Policy:

Animals housed in barrier facilities are required to be maintained in accordance with the AWA's regulations and standards.

In some cases, APHIS inspections of **bonafide** barrier facilities may be performed by analysis of environmental records, visual inspection through an adequate viewing window, and random selection of animals to be visually inspected. Various non-entry methods, such as video viewing from outside the barrier room, may substitute for an inadequate viewing window.

If the APHIS inspector determines it is necessary to enter a barrier room to adequately complete an inspection or to resolve a suspected problem, the inspector may, by following entry procedures normally used by facility personnel, enter and complete the inspection. The inspector cannot be expected to comply with procedures not used by facility employees. The facility must supply a copy of their barrier entry procedures upon request. The facility will need to provide the inspector with protective clothing and items needed to complete the inspection (pens, paper, tape measure, flashlight, etc.).

Prior to an inspection of a barrier facility, the facility may ask the inspector (as part of the standard entry procedure) to verify that he/she has not been in contact with, or exposed to, certain animals for a specified time period.

Such verification is acceptable. Generally, barrier facilities require a period of no animal or specific species contact for 72 hours.

The APHIS inspector **will not** sign any statement in which he or she accepts responsibility for the health of the animals in that barrier facility.

Licensing and Registration of Producers of Antibodies, Sera and/or Other Animal Parts and Pregnant Mare Urine (PMU)

References: 9 CFR, Part 1, Section 1.1 9 CFR, Part 2, Section 2.6(c)

History:Replaces memos dated August 28, 1990, entitled, "Determination of Need for Licensing or Registration for Antibody Production/Serum Collection" and April 17, 1992, entitled, "License Fees for the Production and Sale of Blood Products."

Justification: Clarification of the licensing and/or registration of producers of antibodies, sera or other animal parts. Production of PMU is not covered by the Animal Welfare Act.

Policy:

A facility that produces antibodies or antisera is "testing" animals for their immune response and selects animals for production based on the results of this testing. Therefore, the facility must be **registered** as a research facility.

A facility which harvests or produces only normal blood or sera for regulated purposes is not testing. The facility is selling parts of the animal which is maintained for this purpose. Therefore, the facility meets the definition of a dealer and must be **licensed** as such.

A research facility selling antibodies, antisera, or other body parts for research, teaching, testing, or experimentation, would require a dealer's **license** in addition to its registration. This is not intended to apply to legitimate collaboration between researchers and their exchange and/or transfer of body parts, antibodies, and antisera.

The class B dealer's license fee will be based on the total amount of blood product sales in a year. The cost of the animals will not be deducted from this figure, unless new animals are obtained for every batch of blood products. The table in 9 CFR, Part 2, Section 2.6(c) determines the correct fee.

A license **would not** be required if the research facility only produces antibodies/antisera on a contract basis for particular investigators, not for resale.

Horses used for the production of PMU are not covered by the AWA. This activity is not defined as research, teaching, or testing. People who deal in horses or horse parts are not required to be licensed.

References: AWA Sections 13(a)(3), 13(a)(7), 13(e)(2, 3) and 9 CFR, Part 2, Sections 2.31(d)(1)(i,ii,iii,iv), 2.31(e)(4), 2.33(b)(4) and 9 CFR, Part 3, Section 3.6(b)(5,6,7)

History: Replaces letters dated May 8, 1992, November 7, 1991, November 9, 1990, and March 1, 1990.

Justification: Provides requested guidance. Procedures involving animals will avoid or minimize discomfort, distress and/or pain.

Policy:

A painful procedure is defined as any procedure that would reasonably be expected to cause more than slight or momentary pain and/or distress in a human being to which that procedure is applied. The Institutional Animal Care and Use Committee (IACUC) is responsible for ensuring that investigators have appropriately considered alternatives to any procedures that may cause more than slight or momentary pain or distress. A written narrative description of the methods and sources used to search for alternatives must be provided. Where specific testing procedures are required by Federal law, the CFR references or other legal guidelines requiring them should be noted.

Examples of procedures that can be expected to cause more than momentary or slight pain include, but are not limited to, the following:

- **Terminal Surgery** is considered a painful procedure which is alleviated by anesthesia.
- Freund's Complete Adjuvant used for antibody production may cause results
 ranging from momentary or slight pain to severe pain depending on the product, procedure, and
 species.
- Ocular and Skin Irritancy Testing. The dosing procedure itself is generally not painful but the reaction caused by the product being tested may cause pain.

Examples of procedures that may cause more than momentary or slight distress include, but are not limited to, the following:

- **Food or water deprivation** beyond that necessary for normal presurgical preparation.
- Noxious electrical shock that is not immediately escapable.
- Paralysis or immobility in a conscious animal.

Many procedures, including any of those in the lists above, may cause both pain and distress. An example of a procedure that can be expected to cause more than momentary or slight pain as well as distress would be a study involving extensive irradiation.

Animals exhibiting signs of pain, discomfort, or distress such as decreased appetite/activity level, adverse reactions to touching inoculated areas, open sores/necrotic skin lesions, abscesses, lameness, conjunctivitis, corneal edema, and photophobia are expected to receive appropriate relief unless written scientific justification is provided in the animal activity proposal and approved by the IACUC.

Research facilities must have a mechanism in place for ensuring that animals are reported in the appropriate pain category on the annual report (APHIS Form 7023). Individual animals that do not experience pain/distress from testing procedures should be reported in column C. Individual animals experiencing pain/distress which is alleviated with anesthetics, analgesics, sedatives and/or tranquilizers should be reported in column D. This category includes terminal surgery under anesthesia. Individual animals in which needed anesthetics, analgesics, sedatives, and/or tranquilizers are withheld should be reported in column E. For all column E animals, a written justification, approved by the IACUC, must be provided, including CFR references or other guidelines if appropriate.

Policy #12 — Written Narrative for Alternatives to Painful Procedures — April 14, 1997

References: AWA Section 13(a)(3)(B) and 9 CFR, Part 2, Section 2.31 (d)(1)(ii)

History: Provides requested guidance.

Justification: The Principal Investigator must provide a written narrative of the sources consulted to determine whether or not alternatives exist to procedures which may cause pain or distress.

Policy:

Consideration of alternatives to each procedure which may cause pain or distress must state sources consulted, such as Biological Abstracts, Index Medicus, Medline, the Current Research Information Service (CRIS), and the Animal Welfare Information Center (AWIC).

The minimal written narrative should include: the databases searched or other sources consulted, the date of the search and the years covered by the search, and the key words and/or search strategy used by the Principal Investigator when considering alternatives or descriptions of other methods and sources used to determine that no alternatives were available to the painful or distressful procedure. The narrative should be such that the IACUC can readily assess whether the search topics were appropriate and whether the search was sufficiently thorough.

Reduction, replacement, and refinement (the three R's) must be addressed, not just animal replacement.

Policy #13 — Microchip Implants — April 14, 1997

References: AWA Section 11 and 9 CFR, Part 2, Sections 2.38(g), 2.35(b), 2.50, 2.75(a)

History: Provides requested guidance. Replaces letters dated December 23, 1991 and February 5, 1991.

Justification: All dogs and cats must be identified.

Policy:

For the Animal Care Regional Director to grant a trial approval for a microchip implantation identification system in breeding stock or research animals, the following requirements must be met:

- a. The microchip must be placed in a standard anatomical location.
- b. The microchip scanner device must be readily available to the Animal & Plant Health Inspection Service (APHIS) representative and/or facility employee accompanying the APHIS representative.
- c. The animal identification records must indicate the microchip number, the location on the animal, and the name of the microchip manufacturer.
- d. Any animal with a microchip that goes to another licensee/registrant must have a tag/tattoo if a compatible scanner is not available at the receiving facility.

The Animal Care Regional Director can revoke an approval if the system is found to be ineffective and corrections are not made promptly.

References: AWA Section 13(a)(3)(D,E) and 9 CFR, Part 2, Section 2.31 (d)(1)(x)

History: Provides requested guidance. Replaces letters dated April 21, 1992 and June 5, 1990.

Justification: No animal is to be used in more than one major survival operative procedure except in cases of scientific necessity or veterinary care.

Policy:

No animal assigned to a proposal is to be used in more than one major survival operative procedure unless the multiple procedures are included within one proposal, justified for scientific reasons by the Principal Investigator, and preapproved by the Institutional Animal Care and Use Committee (IACUC). However, an animal that has an emergency major operative procedure as part of proper veterinary care may still be used in a proposal that requires a major survival operative procedure.

A major survival operative procedure must not be performed a second time on an animal in a separate proposal. In order to comply with the intent of the Animal Welfare Act (AWA), animals surviving a major operative procedure must be identified (written documentation) to prevent their use in a second major survival operative procedure.

The AWA and its regulations allow an exemption to limiting animals from being used in only one proposal with a major survival operative procedure. The Institutional Official of the research facility should make the exemption request to the appropriate Animal Care Regional Director, who forwards it to the Animal Care Assistant Deputy Administrator for review and recommendation to the Deputy Administrator. The request for exemption should include the following information:

- a. An outline of the research proposals for which the procedure is requested
- b. The species and the approximate number of animals involved in the exemption request
- c. The time frame for the proposed exempt procedure
- d. The number of major operative procedures to be performed on a given animal, the frequency of such procedures, and the period of time between each major operative procedure
- e. Measures to be taken to ensure that pain/distress are minimized
- f. A complete justification for the exemption in which cost is not normally a major criterion
- g. An assurance that all other stipulated requirements of the AWA and regulations will be met in consideration of this exemption
- h. An assurance that the facility's IACUC has approved the exemption.

The Animal & Plant Health Inspection Service (APHIS) may respond to the formal request by approving the request as written, granting a portion of the request, imposing additional limitations, or denying the request. An annual IACUC evaluation of the exemption is required, which consists of an IACUC assessment of the animals and the effectiveness and soundness of the methods and procedures used. This information is to be included in the report of the IACUC functions. Considerations for the renewal or continuation of the exemption will be based on the IACUC's recommendations following their review. The exemption must be included in the Annual Report (APHIS Form 7023).

References: AWA Section 13(b)(1) and 9 CFR, Part 2, Section 2.31(b)(2,3)

History: Provides requested guidance. Replaces letters dated June 6, 1994 and October 23, 1992.

Justification: To provide clarification of specified individual roles in the Animal Care and Use Program at research facilities.

Policy:

For Animal Welfare Act (AWA) enforcement purposes, the nonaffiliated member of the Insitutional Animal Care and Use Committee (IACUC) is to "provide representation for general community interests." The outside nonaffiliated member cannot be a laboratory animal user at any research facility. Compensation of the nonaffiliated member is permissable only when it does not jeopardize the member's status as a nonaffiliated member. Compensation varies but is normally limited to payment for travel and related expenses, such as parking and meals, to modest monetary payments for participation. The dollar amount of compensation, if any, should not be so substantial as to be considered an important source of income or to influence voting on the IACUC.

The regulations provide for four specific roles within the Animal Care and Use Program:

- 1. Institutional Official
- 2. IACUC Chairperson
- 3. Attending Veterinarian
- 4. Nonaffiliated Member

These positions are meant to provide a system of checks and balances which is not normally achieved if any one person fills more than one of these roles. While the regulations do not specifically prohibit one person from filling more than one role, the Animal and Plant Health Inspection Service (APHIS) strongly discourages such assignments because of the potential for conflicts of interest and/or undue influence by one person over the facility's program. However, a veterinarian who is not the attending veterinarian may assume any one of the other program positions.

No IACUC member can review his/her own proposal.

Policy #16 — Dealers Selling Surgically-Altered Animals to Research — April 14, 1997

References: AWA Section 13(a)(3)(A,B,C,D,E) and 9 CFR, Part 2, Section 2.31 (d)(1)(i,ii,iv,viii,ix,x)

History: Provides requested guidance.

Justification: No animal is to be used in more than one major survival operative procedure except in cases of scientific necessity or veterinary care. The Institutional Animal Care and Use Committee (IACUC) is to ensure that survival surgery will avoid or minimize pain and is aseptically performed by qualified personnel.

Policy:

A dealer performing surgery on animals as a necessary part of a proposed animal activity at a research facility must also register as a research facility and/or be a site of the research facility requesting the altered animals.

Dealers that register as research facilities will comply with all the regulations pertaining to research facilities. Their IACUCs must ensure that all requirements are met before approving the activities associated with the surgical alteration of the animal. If the alteration involves a major operative procedure, the animal must be identified to prevent its use in another major survival operative procedure.

Research facilities that list dealers' premises as sites under their registration are responsible for the animals at the dealers' facilities which are covered under their proposals. The IACUC must inspect all dealers' sites housing animals covered under their proposals. The research facility must also ensure that the person(s) at the dealers' sites performing the proposal procedures is qualified.

Dealers performing routine veterinary care or animal husbandry that involves surgery not required for a research proposal are not required to register as a research facility. Examples include, but are not limited to, neutering, dehorning, and debarking.

References: AWA Section 25, 13(7)(A) and 9 CFR, Part 2, Section 2.36

History: Replaces Regulatory Enforcement and Animal Care (REAC) Memorandum 425 dated September 7, 1995 and August 18, 1993.

Justification: To further explain the Animal Welfare Act (AWA) and regulations regarding the "Animal Welfare Enforcement Report of the Secretary of Agriculture to the President of the Senate and the Speaker of the House of Representatives" hereafter referred to as the "Annual Report to Congress."

Policy:

As required by Section 13 of the Animal Welfare Act (AWA) and further explained in 9 CFR Part 2, Section 2.36, each reporting research facility shall submit an annual report (APHIS Forms 7023 and 7023-A) to the Animal Care Regional Director (ACRD) for the State where the facility is located on or before **December 1** of each calendar year. The annual report shall be signed and certified as correct by the Chief Executive Officer (CEO) or legally responsible Institutional Official (IO). The annual report must include all species covered by the AWA used in research, tests, experiments, or for teaching and those on hand at the end of the U.S. Department of Agriculture (USDA) fiscal year (**October 1 through September 30**). Any annual report not received in the Animal Care Regional office by **December 1** of each year constitutes a violation of 9 CFR, Section 2.36 and the Regional office may initiate appropriate legal action.

The Annual Report to Congress, which is compiled from the research facility annual reports, must assure that professionally acceptable standards governing the care, treatment, and use of animals are being followed; that each principal investigator has considered alternatives to painful procedures; that a summary of any Institutional Animal Care and Use Committee (IACUC) approved exceptions to the regulations or standards is provided; and that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

The research facility annual report must show the number of animals with no pain or distress; the number with pain or distress relieved with anesthetic, analgesic, or tranquilizing drugs; the number with pain or distress not relieved; and the number of animals on hand as of September 30 which were not reported under another category and not assigned to any procedure. For those animals with pain or distress where the appropriate anesthetic, analgesic, or tranquilizing drugs were not used, there must be a detailed statement explaining the procedure producing the pain or distress and the reasons such drugs were not used.

Reporting of animal numbers is based on the USDA fiscal year. Animals are to be counted only once regardless of the number of proposals in which they were used. Animals used in multi-year studies will be counted once each fiscal year. If an animal was used in more than one proposal, it must be counted in the most painful category.

I. Distribution

A. <u>Veterans Administration (VA)</u> - No later than **August 1** of each year, the Animal Care Headquarters must send the appropriate number of APHIS Forms 7023 and 7023-A to the VA at the following address:

Chief, Information Section Research Development Computing Center (RDCC) Veterans Administration Medical Center, 151A 16111 Plummer Street Sepulveda, CA 91343 (818) 895-9431 (office)

B. <u>Federal and USDA Registered Research Facilities</u> - On or before **September 15** of each year, the Animal Care Regional office must send a packet via regular mail containing APHIS Forms 7023 and 7023-A and a notification letter to the legally responsible IO at each USDA registered and Federal research facility <u>other than VA facilities</u>.

II. Instructions for Completing APHIS Forms 7023 and 7023-A

A. APHIS Forms

APHIS Forms 7023 and 7023-A (see attached samples) are three-part forms with one part marked as "Facility Copy" to be retained by the facility. The other two parts are to be forwarded to the AC Regional office for the State in which the facility is located. In order to facilitate proper reporting, facilities with multiple sites should collect and send the annual reports from all sites as one complete unit.

General instructions for the use of the forms are printed on the back. On APHIS Form 7023, all facilities should complete items 1 through 3. Items 4 through 13 should be completed where applicable.

The Continuation Form, APHIS 7023-A, must have items 1, 2, 12, and/or 13 completed. Both forms must have the "assurance statements" at the bottom of the page certified by the signature of the CEO or legally responsible IO.

B. Special Instructions for Column "E"

Entries in Column "E" must be fully explained in statements attached to APHIS Form 7023. At a minimum, these statements should address the following:

- 1. A complete description of the procedure(s) producing pain and/or distress in the animal(s). Cite the name of the test, CFR reference, or other guidelines if appropriate.
- 2. A complete explanation of the reasons why drugs for relieving pain or distress were not used. For example, explain how and/or why drugs would adversely affect the test/study results, or cite all regulation(s) and/or Federal Agency policies that prohibited the use of these drugs.

C. Exceptions to the Regulations and Standards

A summary of IACUC-approved exceptions to the regulations or standards must be attached to APHIS Form 7023. At a minimum, this summary should include the following:

- 1. Identify the IACUC-approved exception(s) to the regulations or standards, including exceptions to the dog exercise plan and/or the nonhuman primate plan for environmental enhancement.
- 2. Describe the IACUC-approved exemption(s).
- 3. Identify the species of animals used.
- 4. Report the number of animals used.

D. Other Information

Column "B" should <u>not</u> be added in the total of animals in Column "F."

It is not necessary to report birds, amphibians, rats of the genus **Rattus** and mice of the genus **Mus** specifically bred for use in research, or other noncovered animals.

Wild rats and mice are covered and must be reported.

Scientific names are not required. Common names are preferred.

The term "Other Farm Animals" refers to farm animals not listed on APHIS Forms 7023 and 7023-A. This would include goats and cattle.

The term "Other Animals" refers to other <u>covered</u> animals. This would include, but not be limited to, animals such as seals, tigers, lions, sloths, kangaroos, opossums, raccoons, wolves, and bobcats.

III. Routing of APHIS Forms 7023 and 7023-A

The routing of completed APHIS Forms 7023 and 7023-A is as follows:

A. VA Facilities

- 1. After receipt of the packet of APHIS Forms 7023 and 7023-A from the Regional office, RDCC will forward the forms to the appropriate VA facilities.
- 2. VA facilities must return the completed forms Part 1, Headquarters and Part 2, Sector office to RDCC; and Part 3, Facility should be retained by the facility.
- 3. No later than **December 1,** RDCC must send the completed APHIS Forms 7023 and 7023-A to the appropriate Regional office for the State in which the VA facility is located.

B. Federal and Other USDA Registered Facilities

- 1. No later than **December 1**, Federal facilities must return the completed Part 1 and Part 2 of APHIS Forms 7023 and 7023-A to the appropriate Regional Office. Part 3 is to be retained by the facility.
- 2. No later than **December 1**, non-Federal USDA registered research facilities must return the completed forms, Part 1 and Part 2, to the appropriate Regional office. Part 3 is to be retained by the facility.

Annual report forms from all facilities must be returned to the appropriate Regional office by **December 1** of each year so that they may be reviewed, returned for correction if necessary, and entered into the database before **December 31** of that year. Reports submitted after **December 31** will not be included in the Annual Report to Congress.

"Headquarters" copies of APHIS Forms 7023 and 7023-A will be retained by the Regional office.

Established deadlines require that Animal Care headquarters develop, draft, and clear the Annual Report to Congress no later than **March 31** of each year.

Samples of the Annual Report form (7023) and its continuation form (7023A) are on the next four pages.

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cases and described to be subject to penalties as provided for in Section 2150.

See reverse side for

Interagency Report Control No. 0180-00A-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

REGISTRATION NO.

FORM APPROVED DMB NO. 0579-0036

 HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA Include Zip Code)

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. REPORTING FACILITY [List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional steeds if necessary.)

FACILITY LOCATIONS (Siles)

٨	Animals Covered By The Animal Welfare Regulations	B. Number of anima's being brod, conditioned, or held for use in teeching, resting, experiments, assearch, or surgery but not yet used for sech purposes.	C Number of animals spon which traching, research, experiments, or lests were conducted implying no pain, distress, or use of pain- releving drugs.	C. Number of animals upon which experiments, teaching, research, surgery, or tests were econducted involving accompanying pain or distress to the animals, and for which apprepriate anesthetic, analgesic, or tranquishing drags were used.		Number of animals upon which teaching, appriments, research, surgery or tests were conducted involving accompanying pain or distinss to the animals and for which the use of appropriate anesthetic, analgesic or tranquituring drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, sergery or tests. (An explanation of the procedures producing pain or distinss in these animals and the reasons such divigs were not used must be attached to this report).	TOTAL NO. OF ANIMALS (Cals. C + D + E)
4.	Dogs				L		
5.	Cats				┡		
6.	Guinea Pigs				-		
7.	Hamsters				-		
В.	Rabons				-		
9.	Non-human Primates	-		-	L	· -	
10.	Sheep	-	1	NAL	D		
17.	Pigs	1		IVIT	H		
12.	Other Farm Animals	~	-		-		
13.	Other Animals						
		-			+	0.00	+

- Professionally acceptable standards governing the care, treatment, and use of animals, including approximate use of anesthetic, analgesic, and tranquitzing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2). Each principal investigator has considered alternatives to painful procedures.
- 3). This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4). The attending veterinarian for this research lackiny has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official) Lordity that the above is true, correct, and complete & U.S.C. Section 21431					
SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL.	NAME & TITLE OF C.E.G. OR INSTITUTIONAL OFFICIAL (Type or Print)	CATE SIGNED			

Public reporting burden for this collection of information is estimated to everage 2 hours per response, including the time for reviewing instructions, searching existing that sources, gettering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this oblication of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, CIFM, Room 404-W, Washington, CIC 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budgett, Washington, CIC. 20503.

INSTRUCTIONS FOR COMPLETION OF APHIS FORM 7023

(Refer to 9 CFR Part 2, Subpart C, Sections 2.33 and 2.36)

- ITEM 1 Enter registration number as assigned to the Research Facility by United States Department of Agriculture (USDA).
- ITEM 2 Enter the complete name and address of the Headquarters Research Facility as registered with USDA.
- ITEM 3 List location of each Facility or Site where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. (Attached additional sheets if necessary.)
- ITEM 4 13 DO NOT enter numbers in Column A. DO NOT add numbers entered in Column B into the total in Column F. Column F is to show total of numbers entered in Columns C + D + E. Entres in Column E must be explained on attached sheet(s).
- ITEM 12 List by common name all other farm animal species.
- ITEM 13 Other: List, by common name, all other warm-blooded animal species covered by the Regulations. (This will include all wild or exotic species.) Attach additional sheets if necessary or use APHIS Form 7023A.
- CERTIFICATION: Must be signed by the Chief Executive Officer (C.E.O.) of the Registered Research Facility or other Institutional Official (I.O.) having authority to legally commit on behalf of the Registered Research Facility. Sign, Print or type Name and Title, and Date.

RETURN COMPLETED FORM WITH AN ORIGINAL SIGNATURE OF C.E.O. OR I.O. TO APPROPRIATE SECTOR OFFICE.

SAMPLE

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to deads and desixt and to be subject to penalties so provided for in Section 2150.

See reverse side for additional information

interapency Report Control In., 0189-00A-AN

UNITED STATES DEPARTMENT OF AGRICULTURE

1. REGISTRATION NO.

FORM APPROVED OMB NO 0579-0036

 HEADQUARTERS RESEARCH FACILITY (Name and Arbress, as registered with USDA Include Zip Code)

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Asimals USED BY C Asimals Covered By The Animal Wetere Regulations 12 &/OR 13. Other (List by species)	B. Humber of animals being beed conditioned, or held for use in reaching, testing, experiments, research, or surgery but not you used for such purposes.	C Number of animals upon which teaching, research, experiments, or lests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distriess to the animals and for which appropriate anesthetic, analysis, or tranquitizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or traits were conducted involving accompanying pain or distance to the animals and for which the use of appropriate anesthetic, analysis, or tranquistoring drugs would have adversely affected the procedures, results, or interpretation of the traching, research, experiments, surgery, or tests. On explanation of the procedures, power or distinct in these animals and the masons such drugs were not used must be attached to this report.	F. TOTAL NO OF ANIMAL (Cols. C - D + E)
	5	A	MF	LE	

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthesic, analgesic, and tranquising drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and requisitors under the Act, and it has required that exceptions to the standards and requisitors be specified and explained by the principal investigator and approved by the institutional Arrmal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the prevision of adequate veterinary cars and to oversee the adequacy of other espects of actional cars and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL. (Chief Executive Officer or Legally Responsible Institutional Official) I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).				
SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED		

Public reporting burden for this collection of information is estimated to average 2 hours per importe, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data sected, and completing and reviewing the collection of information. Seed comments reporting this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Cleanance Office, DRM. Seem 404-W, Washington, D.C. 20503.

20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETION OF APHIS FORM 7023A

(Refer to 9 CFR Part 2, Subpart C, Sections 2.33 and 2.36)

- ITEM 1 Enter registration number as assigned to the Research Facility by United States Department of Agriculture (USDA).
- ITEM 2 Enter the complete name and address of the Headquarters Research Facility as registered with USDA.
- ITEM 12/13 Other: List, by common name, all other warm-blooded animal species covered by the Regulations. (This will include farm species used in biomedical or non-agricultural research, and all wild or exotic species.)

DO NOT enter numbers in Column A. DO NOT add numbers entered in Column B into the total in Column F. Column F is to show total of numbers entered in Columns C + D + E. Entries in Column E must be explained on attached sheet(s).

CERTIFICATION: Must be signed by the Chief Executive Officer (C.E.O.) of the Registered Research Facility or other Institutional Official (I.O.) having authority to logally commit on behalf of the Registered Research Facility. Sign, Print or type Name and Title, and Date.

RETURN COMPLETED FORM WITH AN ORIGINAL SIGNATURE OF C.E.O. OR I.O. TO APPROPRIATE SECTOR OFFICE.

SAMPLE

Policy #18 — Health Certificate for Dogs, Cats, and Nonhuman Primates — April 14, 1997

References: 9 CFR, Part 2, Section 2.78

History: Replaces letter dated March 6, 1992.

Justification: Most dogs and cats transported by a dealer are usually moved for short distances and require only short periods of time in the dealer's private vehicle.

Policy:

A health certificate issued within 10 days of shipment must accompany any dog, cat, or nonhuman primate that is transported in commerce by a licensee or registrant. Regulated dogs, cats, and nonhuman primates transported intrastate by commercial carrier, transported interstate, or in foreign commerce, are required to have properly executed health certificates. However, dogs, cats, and nonhuman primates transported within the State and in the licensee's/registrant's private vehicle may be transported without a health certificate.

Policy #19 — Tattoo Identification of Dogs and Cats — April 14, 1997

References: 9 CFR, Part 2, Sections 2.50(a)(1) and (e)(iii)

History: Replaces REAC Memorandum 430 dated July 20, 1992.

Justification: This policy is to clarify the procedure used in approving tattoo identification of dogs and cats for dealers under the authority of the Animal Welfare Act.

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Policy:

Each licensee who wishes to use a tattoo to identify his/her animals will be assigned a code for identification to include the type of business (Class A or Class B) and the State in which he/she is licensed. Examples of the system are as follows:

Class A dealer from Maryland: MDAA through MDAZZ Class B dealer from Maryland: MDBAA through MDBZZ

In addition to the dealer's code assigned, the dealer will be required to add the necessary numbers to uniquely identify each animal. Dealers of purpose-bred dogs and cats sold only for research purposes may have special tattoos approved by the Administrator.

Policy #20 — Identification of Puppies Less than 16 Weeks of Age — April 14, 1997

References: AWA Sections 1 and 12 and 9CFR, Part 2, Sections 2.50(a)(2) and (b)(3)

History: Replaces memorandum dated December 30, 1993, "Identification of Puppies Under 16 Weeks of Age."

Justification: The Animal Care staff has been made aware of problems from using plastic collars to identify puppies that are less than 16 weeks of age.

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After reviewing the Animal Welfare Act (AWA) and its intent, puppies under 16 weeks of age can be exempt from individual identification if the following requirements are met:

- 1. The puppies remain housed at the facility where they were whelped and are maintained as a litter.
- 2. The enclosure containing the puppies is identified with the information required by 9 CFR Section 2.50 until the puppies are sold or moved from the facility where they were whelped or reach the age of 16 weeks, which ever comes first.